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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,781	09/12/2003	Richard David Guarino	P-5769	5859

32330 7590 06/17/2005

DAVID W. HIGHER, VICE PRESIDENT
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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,781

Applicant(s)

GUARINO ET AL.

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-43 are pending and subject to restriction requirement.

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 13-16 and claims 5-12 (as depending on claim 1), drawn to a surface support coated with 2 materials that are CAR and collagen IV, classified in class 435, subclass 402, for example.
- II. Claims 3, 4 and claims 5-12 (as depending on claim 3), drawn to a surface support coated with 3 materials that are CAR, collagen IV and an additional ECM protein(s), classified in class 435, subclass 402, for example.
- III. Claims 17-19, drawn to a method of making a surface support by treating the surface support with several materials including CAR, collagen IV and/or ECM protein and polycationic polymers, classified in class 435, subclass 402, for example.
- IV. Claims 20, 21, 23-37, drawn to a method for *in vitro* cell proliferating on a surface support coated with 2 materials that are CAR and collagen IV, classified in class 435, subclass 402, for example.
- V. Claims 22, drawn to a method for *in vitro* cell proliferating on a surface support coated with 3 materials that are CAR, collagen IV and an additional ECM protein(s), classified in class 435, subclass 402, for example.

Art Unit: 1651

- VI. Claims 38 and 39, drawn to a method for *in vitro* testing samples or agents that stimulate or inhibit cell proliferation on a surface support coated with 2 materials that are CAR and collagen IV, classified in class 435, subclass 4+, for example.
- VII. Claims 42 and 43, drawn to kit(s) having a surface support coated with 2 materials that are CAR and collagen IV and additional reagents/components suitable for cell growth and proliferation, classified in class 435, subclass 810, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and VII are distinct as claimed because they require presence of different components as claimed. The ECM proteins in addition to the collagen IV material are required for the group II product but they are not necessarily required for the group I product. The additional reagents/components that are suitable for cell growth and proliferation of the group VII are not required for the CAR-containing products of groups II and III as claimed.

Inventions III and Inventions I or II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the support matrices with CAR surfaces or the hyaluronic acid scaffolds can be made to incorporate collagen IV and various combinations with additional material and biologically active molecules, for example: see US 5,939, 323 entire document including example 5 and col. 12, line 42.

Art Unit: 1651

Inventions I or II and Inventions IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case matrices with CAR surfaces or the hyaluronic acid scaffolds comprising collagen IV and BMPs, for example, can be used for bone and cartilage repairs as taught by US 5,939, 323 (example 5 and col. 12, lines 42-54).

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of species

This application contains claims directed to the following patentably distinct species of the claimed invention that are several or various CAR materials as recited in the instant claim 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species that is one CAR material from the list of CAR materials recited in the instant claim 5 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 or 3 are generic.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

Art Unit: 1651

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

June 15, 2005

A handwritten signature in black ink, appearing to read 'V. Afremova', with a stylized flourish at the end.

VERA AFREMOVA

PRIMARY EXAMINER